Compliance Guidance

Mammography Facility Survey and Medical Physicist Qualification Requirements Under MQSA

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U.S. Department Of Health And Human Services
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Inspection Support Branch
Division of Mammography Quality
and Radiation Programs
Office of Health and Industry Programs

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Charles Gunzburg, Division of Mammography Quality and Radiation Programs, HFZ-240, 1350 Piccard Drive, Rockville, MD 20850. Comments may not be acted upon by the Agency until the document is next revised or updated. For questions regarding the use or interpretation of this guidance contact Charles Gunzburg at 301-594-3332.

Additional Copies

World Wide Web/CDRH home page at http://www.fda.gov/cdrh/dmqrp.html or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111 from a touch-tone telephone. At the first voice prompt press 1 to access DSMA Facts, at second voice prompt press 2, and then enter the document number 6409. Then follow the remaining voice prompts to complete your request.

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Background

The Mammography Quality Standards Act was passed on October 27, 1992, to establish national quality standards for mammography. The MQSA required that to provide mammography services legally after October 1, 1994, all facilities, except facilities of the Department of Veterans Affairs, must be accredited by an approved accreditation body and certified by the Secretary of Health and Human Services (the Secretary). The authority to approve accreditation bodies and to certify facilities was delegated by the Secretary to the FDA. On October 28, 1997, the FDA published the MQSA final regulations in the *Federal Register*. The final regulations became effective **April 28, 1999**, and replaced the interim regulations (58 FR 67558 and 58 FR 67565).

The FDA is planning a variety of efforts to educate the public about the final regulations. These efforts include making presentations at key professional meetings and providing written materials to the public. The currently available written documents include the *Small Entity Compliance Guide* (October 1997), a quarterly newsletter *Mammography Matters*, and an Internet home page (http://www.fda.gov/cdrh/dmqrp.html).

1 This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

Introduction

This document is intended to provide guidance to mammography facilities and their personnel. It represents the Food and Drug Administration's (FDA) current thinking on the final regulations implementing the Mammography Quality Standards Act (MQSA) (Pub. L. 102-539). The FDA uses mandatory language, such as shall, must, and require, when referring to statutory or regulatory requirements. The FDA uses non-mandatory language, such as should, may, can, and recommend when referring to guidance. It is the responsibility of the facility to read, understand, and follow the final regulations. This guidance uses a question-and-answer format to provide information about how FDA will implement its mammography program under the regulations and MQSA.

Under its own authority, a state may impose more stringent requirements beyond those specified under MQSA and its implementing regulations. A facility may want to check with the state or local authorities regarding their requirements.

MAMMOGRAPHY FACILITY SURVEY AND MEDICAL PHYSICIST QUALIFICATION REQUIREMENTS UNDER MQSA

The MQSA Requirements for the Mammography Facility Survey

On October 28, 1997, the Food and Drug Administration published the final regulations under the Mammography Quality Standards Act of 1992 (MQSA). These regulations, and MQSA itself, require that each certified facility undergo an on-site physics consultation and evaluation survey performed by a qualified medical physicist. The physicist's survey must include several specific items and the physicist must provide the facility with a report.

The regulations also require that a medical physicist perform equipment evaluations, when such evaluations are necessary. A brief discussion of the requirements and scope of these evaluations in included.

Before a medical physicist can conduct either the annual survey or equipment evaluations, he/she must meet the initial and continuing education and experience requirements under the regulations. These requirements are reviewed in the section dedicated to the physicist qualifications.

The regulations covering these three areas are included as Attachments A, B, and C for the convenience of the reader. Each citation referenced in this document may be found in one of those three attachments.

For more detailed information, please refer to the Policy Guidance Help System on the MQSA Internet site, http://www.fda.gov/cdrh/dmqrp.html.

MQSA Requirements for the Mammography Facility Survey

The material in this section reviews the following:

- MQSA requirements for facilities to use a medical physicist,
- requirement for the completion and the content of the annual survey report, and
- items the MQSA inspectors routinely look for when reviewing the survey report during inspections.

Requirements for the Services of a Medical Physicist

Each certified mammography facility is required to utilize the services of a qualified medical physicist to survey the facility's equipment and to oversee the equipment-related quality control (QC) program used by the facility. The facility is also required to have any equipment that is new to the facility, reassembled, or has undergone any major repair (including component replacement) evaluated by a medical physicist. These regulations are included as Attachment A.

Required Frequency of the Survey

The medical physicist's survey must be performed "once every twelve months." This requirement satisfies MQSA, which requires an annual survey, and the final regulations, which specify that the survey must be conducted at least "once a year."

MQSA inspectors are instructed that the facility meets this requirement if, at the time of the inspection, the most recent survey was conducted within 14 months of the previous survey. FDA selected this approach to provide facilities and physicists some flexibility in scheduling the surveys.

What A Complete Survey Must Include

The medical physicist is responsible for performing the facility's survey and providing the facility with the survey report.

The regulations (see 900.12(e)(9) in Attachment A) contain a listing of the required testing and evaluation. The survey report must be dated with the actual survey date(s) and include the name of the medical physicist performing or supervising the survey, as well as any other individual who participated in the survey under the direct supervision of the medical physicist. If the survey is done over a period of time, the physicist must indicate in the report the dates of completion of the individual part, not only the date the final report is generated or delivered. While a report may contain both the survey and report dates, the survey date(s) should be clearly identified. No part of the survey can be more than 14 months old at the time of the inspection.

The survey must contain the following;

A. All testing specified in the list of the annual QC tests:
- Automatic exposure control (AEC) performance,
- Kilovoltage peak (kVp) accuracy and reproducibility,
- Focal spot condition or system resolution test,
- Half-value layer test,
- Coefficient of variation (COV) for the breast entrance air kerma,
- COV for the AEC reproducibility,
- Average glandular dose calculation,
- X-ray/light-field (where applicable)/image receptor/compression paddle alignment,
- Screen speed uniformity,
- System artifacts,
- Radiation output,
- Decompression (compression release),
- Non screen-film units must include all testing specified by the manufacturer.

B. The phantom image quality test described under the weekly quality control requirements (the physicist must perform the phantom image test for each unit evaluated during the survey).

C. An evaluation of the facility quality control testing performed since the last survey and any written documentation regarding corrective actions taken, including the results of any such corrective actions.

The survey report must contain the following:

- A summary of the annual test results listed above, including pass/fail designations and numerical results, where applicable,
- A summary of the evaluation of the facility QC testing (other than annual) with any recommendations for necessary improvements and/or corrective actions, as needed,
- The date the survey was conducted,
- The name(s) of the medical physicist performing or supervising the survey as well as any other individual participating in the survey under the direct supervision of the medical physicist.

The survey report must contain sufficient information documenting that each test was conducted according to the requirements. For example, when reporting the dose calculations, the report should contain information regarding the kVp at which the HVL and the dose were obtained. If such information is not included, then copies of the data collected during the survey showing all measurement parameters must be provided along with the report.

Table 1 lists the required testing that must be addressed in the survey. Each item is listed by its common name and the subpart of 900.12(e) where the requirement is listed. This table was adapted from one included in the "Compliance Guidance - The Mammography Quality Standards Act Final Regulations," referenced above.

Timeliness of the Survey Report

The physicist's survey report must be sent to the facility within 30 days of the survey. However, it is imperative that the medical physicist notify the facility immediately of any test failures or problems. Failures or problems concerning QC tests referenced in paragraph 900.12(e)(8)(ii)(B) (Attachment B) must be corrected within 30 days of the test date. However, facilities are required to correct all problems listed below (see paragraph 900.12(e)(8)(ii)(A)) "before any further examinations are performed or any films are processed using the component of the mammography system that failed the test...."

- Daily QC tests *(e)(1),*
  - Base plus fog
  - Mid-density
  - Density difference
- Weekly QC tests *(e)(2),*
  - Phantom image quality (also performed as a part of the physicist survey)
- Semiannual QC tests *(e)(4)*
  - Darkroom fog *(e)(4)(i),*
  - Screen-film contact *(e)(4)(ii),*
  - Compression device performance *(e)(4)(iii),*
- Annual QC tests *(e)(5)*
  - Dose *(e)(5)(vi),*
- Other modalities *(e)(6),* and
- Mobile units *(e)(7)*

Although most of the problems requiring immediate attention are not included in the physicist's survey, the physicist may become aware of such problems during the course of the survey. In this case it is imperative that the physicist notify the facility immediately. If the violations require repair within 30 days, the physicist should inform the facility about these problems in a timely fashion. The physicist is encouraged to work with the facility to ensure that any problems found are corrected within the regulatory limit. One mechanism to aid in this process would be for the physicist, immediately after the completion of the survey, to provide the facility with a list of the tests that failed and any additional problems found.

Calibration of Air Kerma Measuring Instruments

The air kerma measuring instruments used by the medical physicist must be calibrated at least once every two years and each time the instrument is repaired. The instrument must be calibrated to an accuracy of ± 6 percent (95 percent confidence level) in the mammography energy range. The calibration must occur at the National Institute for Science and Technology (NIST) or a calibration laboratory that participates in a proficiency program with NIST. The calibration of the physicist's instrument must have been completed within 12 months of the completion of the calibration laboratory proficiency test and that test must have shown the laboratory to be within ± 3% of the national standard in the mammography energy range. We recommend that the medical physicist provide information regarding the calibration of his/her air kerma measuring instruments in the survey report.

Table 1: Tests Required for the Annual Survey

Test	*Regulatory Action Levels*	*Scope **	*Timing of required corrective action***
AEC performance capability (e)(5)(i)	*OD exceeds the mean by more than ± 0.30 (over 2-6 cm homogeneous material thickness range), or the phantom image density at center is less than 1.20 [±0.30 changes to ± 0.15 on October 28, 2002]*	*All machines, all clinically used target/filter combinations; Thickness tracking (2-6 cm, appropriate kVp's); kVp Tracking (clinical range) 6-8 cm phantoms for Rh-Rh & W-Rh w/appropriate kVp's*	*Within 30 days of the date of the test.*
KVp accuracy and reproducibility (e)(5)(ii)	*Exceeds ± 5% of indicated or selected kVp COV exceeds 0.02*	*All machines at 3 clinical kVp's – lowest measurable, most frequently used clinically, and highest obtainable*	*"*
Focal spot (e)(5)(iii)	*See regulations for focal spot sizes and/or the resolution requirement*	*All machines, each clinically used screen/film combinations; All clinically used target materials and focal spots; Most commonly used SID*	*"*
HVL (e)(5)(iv)	*See table in regulations*	*All machines, all clinically used targets & filters*	*"*
Air kerma and AEC reproducibility (e)(5)(v)	*Reproducibility COV exceeds 0.05*	*All machines*	*"*
Dose (e)(5)(vi)	*Exceeds 3.0 mGy (0.3 rad) per exposure*	*All machines, all clinically used screen/film combinations, all targets & filters used clinically for a standard breast*	*Before further examinations are performed with unit*
X-ray field / light field / compression device alignment (e)(5)(vii)	*Exceeds 2% SID at chest wall Paddle visible on image or paddle outside IR > 1%*	*All machines, all clinically used collimators, all target materials and focal spots*	*Within 30 days of the date of the test*
Screen speed uniformity (e)(5)(viii)	*OD variation exceeds 0.30 from the maximum to the minimum*	*All cassettes – may be grouped by size and speed – limit holds within groups – groups must be identifiable to the technologist*	*"*
System artifacts (e)(5)(ix)	*Determined by physicist*	*All machines, all cassette sizes, all clinically used focal spots & target/filter combinations*	*"*
Radiation output (e)(5)(x)	*Less than 4.5 mG [changes to 7.0 mGy October 28, 2002]*	*All machines*	*"*
Automatic decompression control (e)(5)(xi)	*Failure of override or manual release or status indication*	*All machines (if auto is provided)*	*"*
Any applicable tests for other modalities (e)(6)	*Action levels specified by equipment manufacturers*	*All machines*	*Before further examinations are performed with unit*
Phantom image quality test (e)(9) see (e)(2)	*As specified by the facility's accreditation body*	*All machines, all target/ filter combinations where the average breast is imaged and all screen/film combinations used clinically for the average breast*	*Before further examinations are performed with unit*

***** Many of the items in this column are based on the DRAFT Compliance Guidance Document #2 that is under public comment at the time of this publication. If changes result from that public comment, this document will be revised. The final version will be available on the Internet site (http://www.fda.gov/cdrh/dmqrp.html).

** Refer to 900.12(e)(8)(ii)(A) or (B) as applicable

Evaluation of the Survey Report by the MQSA Inspector

Inspection Questions Related to the Survey

We have generated the following checklist from questions covering the physicist survey that will normally be addressed during the annual MQSA inspection. Included are items relevant to the inspector's evaluation of the survey, the physicist's qualifications, and the facility response to any physicist recommendations.

- *Survey report available?*
- *Date of previous survey*
- *Date of current survey*
- *Survey conducted, assisted, or supervised by (names)*
- *Survey complete?*
  - *Pass/fail list*
  - *Recommendations for failed items*
  - *Physicist's evaluation of technologist's QC tests*
    - *Processor QC?* [for each processor]
    - *Phantom image?* [for each x-ray unit]
    - *Repeat analysis?*
    - *Analysis of fixer retention?* [for each processor]
    - *Darkroom fog?* [for each darkroom]
    - *Screen-film contact?* [for all cassettes]
    - *Compression?* [for each x-ray unit]
  - *Collimation*
    - *X-ray field - light field alignment*
    - *X-ray field - image receptor alignment*
    - *Compression device/image receptor edge alignment (chest wall)*
  - *Focal spot size/resolution measurement*
    - *Done for all clinically used focal spots?*
      - *Numerical Results Given?*
  - *kVp Accuracy*
    - *Done at the lowest clinical value measurable, most often used clinically, and highest available kVp?*
      - *Numerical results given?*
  - *kVp Reproducibility*
    - *Done at the kVp most commonly used clinically? [Regulations specify additional kVp's,]*
      - *Numerical results given?*
  - *Beam quality (HVL) measurement*
    - *Done at the kVp most commonly used clinically?*
      - *Numerical results given?*
  - *AEC performance*
    - *Reproducibility*
      - *Numerical results given?*
    - *Performance capability*

        - *Done for 2, 4, and 6 cm [at typical kVp(s) for these thicknesses]*
        - *Numerical results given?*
    - *Uniformity of screen speed* [for all cassettes used]
        - *Numerical results given?*
    - *Dose (including entrance air kerma & reproducibility)*
        - *Exposure & HVL at same clinical kVp?*
        - *RMI-156 or equivalent phantom?*
        - *Numerical results given?*
    - *Phantom Image*
        - *Done at the kVp normally used clinically?*
        - *RMI-156 or equivalent phantom?*
        - *3 object scores given?*
    - *Artifact evaluation*
    - *Radiation output*
    - *Decompression*
    - *QC Tests - other modalities (if applicable)*
- *Action taken? (if called for in survey report)*

MQSA inspectors will usually determine only if the survey documentation contains a clear indication that:

- The physicist performed each test or review (in the case of the facility QC review) and that a "pass" or "fail" was recorded for each test and QC item;
- The physicist provided numerical test results (such as COV, kVp accuracy and AEC reproducibility, HVL value, dose value, etc.) to the facility; and
- The report contains a summary of the findings, along with recommendations when the findings indicate that one or more of the tests or reviews have not "passed."

The "recommendations" included in the summary need not be limited to items specifically covered by the survey. The report may include any recommendations resulting from the review of the QC test program or other sources that the physicist believes might improve quality of mammography at the facility. However, the facility is required to implement only those items necessary to assure the facility's compliance with the regulations.

Requirements for Equipment Evaluation

When a mammography facility installs new radiographic equipment or processors, this equipment must be evaluated by a qualified medical physicist before being placed in service. In this context, "new" means "new to the facility" and, therefore, includes used equipment. Equipment evaluations (Attachment A) must also be performed whenever such equipment is disassembled and then reassembled at the same or a new location or whenever a major component is changed or repaired. The equipment evaluation is required even if a full survey has recently been completed to verify that all functions, which may have been affected by the change or repair, have been successfully restored.

Examples of major changes or repairs that would call for equipment evaluations include, but are not limited to:

- Replacement of an x-ray tube, collimator, filter, AEC, or AEC sensor.
- A total overhaul of the processor.

Routine preventive maintenance, pump replacement, replacement of the developer or fixer racks, replacement of the control board or changes in chemistry brand are not considered to be major changes or repairs and, consequently, would not require evaluation by a medical physicist.

In cases where questions arise as to whether an equipment evaluation should be performed, the facility must follow its accreditation body's criteria. Therefore, if changes or repairs to the system are anticipated, the facility should contact its accreditation body to inquire whether the change affects a major component and, therefore, requires an evaluation.

These evaluations are used by the facility, its accreditation body, and the MQSA inspector to determine whether the new or changed equipment meet the requirements of applicable standards in 900.12(b) and (e). Consequently, the physicist must provide the facility with sufficient documentation that clarifies both the testing performed and the test results. The medical physicist (after consultation with the facility's accreditation body and/or FDA, if necessary) should decide which tests need to be performed following a particular repair, and should be prepared to explain the rationale behind his/her decision. Before the new or changed equipment is put into service for patient examinations or processing mammograms, the facility must correct all problems relating to the regulations. There is no provision for a 30-day correction period such as with some QC and physics survey test results.

Scope of the Equipment Evaluation

The equipment evaluation is more extensive than the survey. It may be regarded as an "acceptance" test for the equipment and an annual survey alone is not sufficient to meet this requirement. The evaluation must address all applicable requirements under the equipment section of the regulations (900.12(b)) as well as all applicable QC requirements and testing under 900.12(e), including applicable daily, weekly, quarterly, semiannual, and annual QC tests. Such testing is only applicable to the specific equipment that is repaired, replaced, moved, or added and it is not applicable to other equipment in the facility that has not been affected.

FOR MORE INFORMATION

FDA maintains an MQSA Internet site at http://www.fda.gov/cdrh/dmqrp.html. The site contains many useful items, including current information about the mammography program and the on-line policy guidance Help System. If you have questions on how to prepare for inspections, call FDA's Facility Hotline at (800) 838-7715, or FAX your request to (410) 290-6351.

MQSA Medical Physicists Qualification Requirements

During the annual MQSA inspection, the inspector will evaluate the medical physicist's qualifications against the requirements in the MQSA and the regulations published October 28, 1997 (see 900.12(a)(3)-Attachment C). All medical physicists, including those who were board certified, State licensed, or State approved prior to April 28, 1999, will be evaluated.

There are no "grandparenting" provisions in the final MQSA regulations covering the medical physicist and **ALL** physicists qualified prior to April 28, 1999, have additional criteria for qualification under the final regulations.

The qualifications for the medical physicist are relatively complicated. As an aid to understanding them, we have separated the medical physicist section into three parts.

- **A.** The requirements for those physicists who are qualifying through the "master's degree or higher" route
- **B.** The requirements for those who are qualifying through the "alternative initial requirements" approach covering education, training, and experience
- **C.** The continuing qualification requirements applicable to all physicists

All qualifying medical physicists must demonstrate compliance with either "A" or "B" below. The continuing education and experience requirements covered in "C" are applicable to all physicists.

A. All medical physicists qualifying under the "master's degree or higher" route must demonstrate:

1. a. Licensure or approval: Be licensed or approved by a State to perform mammography surveys.

OR

b. Board Certification: Be certified in diagnostic medical physics or medical physics by one of the following:

i. The American Board of Radiology (ABR)
ii. The American Board of Medical Physics (ABMP)

AND

2. Education, training, and experience:

a. Degree: Have at least a master's degree or higher in a physical science with at least 20 semester hours (30 quarter hours) of graduate or undergraduate physics.

AND

b. Survey Training: Have at least 20 contact hours of mammography facility survey training.

AND

c. Initial Experience: Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units.

B. Certain medical physicists may have qualified under the interim regulations before April 28, 1999, through the State approval or licensing mechanism or through the professional certification route without having the appropriate degree to meet the final regulations as described above. Such medical physicists may qualify under the "**Alternative Initial Qualifications"** route. Such individuals must demonstrate that, by April 28, 1999, they have achieved compliance with the following:

1. a. Licensure or approval: Be licensed or approved by a State to perform mammography surveys.

OR

b. Board Certification: Be certified in diagnostic medical physics or medical physics by one of the following:

i. The American Board of Radiology (ABR)
ii. The American Board of Medical Physics (ABMP)

AND

2. Education, training, and experience:

a. Degree: Have a bachelor's degree in a physical science with at least 10 semester hours (15 quarter hours) of graduate or undergraduate physics. (This would include individuals having advanced degrees in non-physical science fields.)

AND

b. Survey Training: Have at least 40 contact hours of mammography facility survey training. This training must have occurred after fulfilling the degree requirement in 2.a.

AND

c. Initial Experience: Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. This initial experience must have occurred after fulfilling the degree requirement in 2.a,

C. All medical physicists must meet the following requirements:

1. New Mammographic Modality: Before a physicist may begin independently performing surveys or equipment evaluations on any mammographic modalities in which the physicist was not previously trained (e.g., xeromammography, digital mammography, screen-film mammography), the physicist must have at least 8 hours of training in the modality.

AND

2. Continuing Experience: The physicist must have conducted a minimum of two mammography facility surveys and a total of six mammography unit surveys (or equipment evaluations which cover all of the equipment survey items) during the 24 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection, or any date in between the two.

The starting date for this requirement is April 28, 1999, or the date on which the physicist initially qualifies to work independently, whichever is later. Failure to meet the physicist's continuing experience requirement will not be considered a noncompliance until the later of July 1, 2001, or 24 months after the physicist's starting date.

AND

3. Continuing Education: Have taught or completed at least 15 continuing education units in medical physics or mammography during the 36 months immediately preceding the date of the facility's annual MQSA inspection, or the last day of the calendar quarter preceding the inspection, or any date in between the two. The continuing education must include training appropriate to each mammographic modality evaluated by the medical physicist. CEUs earned through teaching a course can be counted only once toward meeting the 15 units required in any 36-month period.

The starting date for this requirement is October 1, 1994, or the date on which the physicist initially qualifies to work independently, whichever is later. Failure to meet the physicist's continuing education requirement will not be considered a noncompliance until 36 months after the physicist's starting date.

NOTE: For meeting the requirements in items A.2.b., A.2.c., B.2.b., B.2.c., and C.2., FDA allows multiple testing of the same mammography unit. However, no more than one survey of a specific facility within a 10-month period can be counted toward the total requirement, and tests of the same unit cannot be counted more than once in any consecutive 60-day period. It is

important enough to repeat that, for the alternative initial qualifications route, the training and experience in items B.2.b. and B.2.c. must have been obtained after the qualifying degree requirements are satisfied and before April 28, 1999.

Additional Guidance

Alternative Initial Qualification

This area is of particular concern for some medical physicists. Those who qualified under the interim regulations using only the state liscensure or approval mechanism and those using the professional certification provision who do not meet the degree requirements under the April 28, 1999, regulations must meet the requirements of the "Alternative Initial Qualifications." This provision specifies that, before these individuals can perform MQSA facility surveys, they must meet the following requirements:

- Have a bachelor's degree or higher, in a physical science
- Have a minimum of 10 semester hours (or equivalent) of college level physics
- Have 40 contact hours of documented specialized training conducting mammography facility surveys
- Have performed surveys on at least one mammography facility and a total of at least 20 mammography units
- Have obtained the initial survey training and experience must occur <u>after</u> meeting the degree requirement

All of the above must have been completed by the April 28, 1999, deadline.

Qualifying Degree

All qualifying degrees must be from the physical sciences. In this context, a physical science degree means a degree in one of the specialties or subspecialties of physics, chemistry, radiation science, or engineering. All subspecialties in radiation science that involve the study or use of radiation may be considered as a radiation science degree.

Again, for those physicists qualifying with a bachelor's degree, **both** the 40 hours of training and the experience requirements must be met **after** completing the degree requirements.

Specialized Training

Physicists may use various types of training to meet the requirement for specialized training in conducting surveys, including continuing education units (CEU), formal academic training, or other types of training programs.

For meeting the continuing education requirement for physicists, FDA accepts CEU credits or units related either to the diagnosis and/or treatment of breast disease or to areas that will aid medical physicists in improving the quality of the survey. To satisfy the specialized survey training requirements, CEUs must be specifically related to technical or quality assurance topics pertinent to mammography facility surveys. Therefore, not all CEUs, acceptable as continuing education units, will satisfy the requirement for specialized training.

Physicists who qualified and obtained their survey training prior to April 28, 1999, may count the survey training for both CEUs and the "specialized training in conducting surveys" requirement. However, physicists who complete their qualifications after April 28, 1999, may only use the survey training to meet their initial requirements and may not use the training as CEUs.

Physicists who originally qualified using the education, training, and experience route under the interim regulations will meet the final regulations requirements if their experience included at least 10 mammography unit surveys and 1 complete facility survey, including the evaluation of technologist QC records.

Direct Supervision

After April 28, 1999, the regulations require that the initial survey experience be under the direct supervision of a medical physicist who qualified under 900.12(a)(3)(i) and (iii). This means that, after that date physicists who qualified under the “alternate initial qualifications” (900.12(a)(ii)) will no longer be able to provide the direct supervision required for the initial or requalification experience requirement. Physicists who initially qualify under the alternative route, and who subsequently upgrade their educational background and/or their professional certification status so that they now qualify under the requirements at 900.12(a)(3)(i) and (iii), may provide this required supervision. The qualifications of such individuals are equal to those who initially qualify under 900.12(a)(3)(i) and (iii). However, the initial qualification date for these physicists will remain unchanged.

MQSA requires that the survey be conducted by or under the direct supervision of a qualified medical physicist. For physicists, direct supervision means that the supervisor is present to observe and correct, as needed, the performance of the individual being supervised. Therefore, to meet this requirement the supervisor must be in the room during the time each survey item is being performed.

New Mammographic Modality Training

After April 28, 1999, before a medical physicist may begin independently surveying or performing equipment evaluations on a mammographic new modality for radiography of the breast, he/she must obtain 8 hours of training in surveying that new mammographic modality. FDA defines a new modality as a technology for which the physicist has not been previously trained. If the physicist started using this mammographic modality before April 28, 1999, the 8-hour training requirement does not apply. The physicist can obtain the required training from many sources, including, but not limited to, special training courses, continuing education, and training provided by the manufacturer of the mammographic modality.

Initial and Continuing Experience

FDA recognizes that some physicists may be unable to visit multiple facilities to meet the experience requirements. FDA, therefore, allows the survey of the same facility and the same mammography units to count towards the total requirements for initial, continuing, and re-qualification training and experience. However, there are restrictions on the frequency under which such re-surveying will be allowed. For the unit survey requirements in each of these categories, physicists can count no more than one survey of any single unit in any 60-day period towards the total. For both the continuing experience and re-qualification requirements, the physicist can count no more than one survey of a specific facility in any 10-month period.

Continuing Education

FDA has placed additional requirements in the continuing education regulations as they relate to the medical physicist. The medical physicist must have completed at least 15 CEUs **AND** must also have, in the 36 months preceding the inspection (or the last day of the calendar quarter preceding the inspection or any date in between the two), accrued some hours in each mammographic modality for which he/she provides medical physics support. As discussed above, all CEUs related to the diagnosis or treatment of breast disease or other areas that will aid facility personnel in improving the quality of mammography may be acceptable toward meeting the continuing education requirement. Diagnostic medical physics continuing education that is not directly related to mammography or general continuing education in mammography that is unrelated to medical physics may also be acceptable. However, physicists must make sure they obtain continuing education appropriate to each mammographic modality evaluated in their practice as a mammography medical physicist, even if this action causes the required total to exceed 15 hours.

Documentation

It is the responsibility of the facility to have adequate documentation available to establish the physicist's qualifications. This documentation must include information covering the initial qualifications, the continuing experience, and continuing education for the medical physicist. The physicist should assist in this process by providing the necessary materials to each facility where they provide professional services. At the time of the inspection, the continuing education and

experience for the medical physicist must include 15 CEUs in the previous 36 months and the survey of at least two facilities and six units in the previous 24 months. The medical physicist should be aware that each facility may elect to maintain their personnel continuing experience and continuing education records on different time schedules and should attempt to provide the necessary information to each facility in a timely manner. Table 2 lists examples of acceptable documentation for the medical physicist.

Table 2: Acceptable Documentation for the Medical Physicist's Qualifications

Requirement	Obtained Prior to 10/1/94	Obtained 10/1/94-4/28/99	Obtained After 4/28/99
State Licensure or Approval	1. State license or approval/copy with expiration date 2. Confirming letter from State licensing board	1. State license or approval/copy with expiration date 2. Confirming letter from State licensing board	1. State license or approval/copy with expiration date 2. Confirming letter from State licensing board
Board Certification (ABR or ABMP)	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR	1. Original/copy of certificate 2. Confirming letter from certifying board 3. Pocket card/copy of certificate 4. Confirming letter from ACR
Degree in a physical science-final regs (Master's pathway) (Bachelor's pathway -alternative)	1. Original/copy of diploma 2. Confirming letter from college or university	1. Original/copy of diploma 2. Confirming letter from college or university	1. Original/copy of diploma 2. Confirming letter from college or university
Initial physics education-final regs (20 semester hours) (10 semester hours -alternative)	1. College or university transcripts 2. Confirming letter from college or university	1. College or university transcripts 2. Confirming letter from college or university	1. College or university transcripts 2. Confirming letter from college or university
Survey Training-final regs (20 contact hours) (40 contact hours -alternative)	1. Attestation 2. Letter or other document from training program 3. CME/CEU in mammography or medical physics 4. Letter or other document confirming in-house or formal training 5. Training gained performing surveys	1. Letter or other document from training program 2. CME/CEU in mammography or medical physics 3. Letter or other document confirming in-house or formal training 4. Training gained performing surveys	1. Letter or other document from training program 2. CME/CEU in mammography or medical physics 3. Letter or other document confirming in-house or formal training 4. Training gained performing supervised surveys
Initial Experience-final regs (1 facility-10 units) (1 facility-20 units -alternative)	1. Attestation 2. Copy or coversheet of survey 3. Letter from facility or listing from company providing the physics survey services documenting performance of survey done	1. Copy or coversheet of survey 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done	1. Copy or coversheet of survey done under direct supervision 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under direct supervision
Initial Mammography Modality Specific training (8 hours-final regs)	1. Attestation 2. Mammography modality specific CME/CEU certificates 3. CME/CEU certificates plus agenda, course outline, or syllabus 4. Confirming letters from CME/CEU granting organizations 5. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. Mammography modality specific CME/CEU certificates 2. CME/CEU certificates plus agenda, course outline, or syllabus 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. Mammography modality specific CME/CEU certificates 2. CME/CEU certificates plus agenda, course outline, or syllabus 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses
Continuing Experience (2 facilities-6 units/24 months-final regs)	N/A	N/A	1. Copy or coversheet of survey 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done
Continuing Education (15 CME/36 months)	N/A	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates, or other documents from manufacturers' or other formal training courses
Continuing Mammographic Modality Specific Education-final regs	N/A	1. Mammography modality specific CME/CEU certificates 2. CME/CEU certificates (plus agenda, course outline, or syllabus) 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. Mammography Modality Specific CME/CEU certificates 2. CME/CEU certificates (plus agenda, course outline, or syllabus) 3. Confirming letters from CME/CEU granting organizations 4. Letters, certificates, or other documents from manufacturers' or other formal training courses
Requalification-Experience–final regs–done under direct supervision	N/A	N/A	1. Copy or coversheet of survey done under direct supervision 2. Letter from facility or listing from company providing the physics survey services documenting performance of survey done under direct supervision
Requalification- Education	N/A	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates, or other documents from manufacturers' or other formal training courses	1. CME/CEU certificates 2. Confirming letters from CME/CEU granting organizations 3. Letters, certificates, or other documents from manufacturers' or other formal training courses

Attestation

Individuals attempting to establish their qualifications as medical physicists may attest to certain training and experience requirements that were obtained prior to October 1, 1994. In addition, FDA will also accept attestation from medical physicists in situations where a continuing education provider does not specifically document the applicability of their CEUs to mammography. The attestation must include documentation showing the total number of CEUs earned in the program and documentation showing the total number of CEUs specific to mammography that were available. FDA will not accept attestation for establishing any qualifying degree requirements, including the required number of hours in physics, even if these conditions were satisfied prior to October 1, 1994. All attestations must be in the proper format. We have included a sample as Attachment D.

Inspection

Both MQSA and the regulations require that the survey be conducted by a medical physicist who meets specific qualification requirements. MQSA inspectors are required to confirm that the report of the annual survey is signed by (or contains the identification of) the qualified medical physicist who actually conducted or directly supervised the conduct of the survey. It is not a requirement that the report contain a handwritten signature; rather, the report must indicate the name of the fully qualified medical physicist who conducted or directly supervised the conduct of the survey. If other personnel assisted in the survey (an assistant, a trainee, or person attempting to meet the experience requirements) their name(s) must be included. **In the case of such training surveys, FDA will assess the qualifications of the supervising medical physicist during the inspection.**

Inspection Questions Related to the Physicists Qualifications

The following items are adapted from questions the inspector will routinely complete during the annual MQSA inspection.

- **Evaluation**
  - Qualifying Degree
    - **Master's** (or higher)
    - **Bachelor's**
    - **No Degree**

- *If you checked Master's or higher:*
  - **Initial Qualification Requirements met?**
    - Certified (OR)
    - State licensed or approved
    - Master's degree in a physical science (w/20 semester hours in physics)
    - 20 contact hours training
    - experience in conducting surveys (1 facility & 10 units)

- *If you checked Bachelor's:*
  - **Qualified under interim rules?** (prior to 4/28/99)
    - Certified (OR)
    - State licensed or approved
    - Bachelor's degree in a physical science (w/10 semester hours in physics), (physical science: physics, chemistry, engineering, radiation science)
    - 40 contact hours. training in surveys (after Bachelor's)
    - experience in conducting surveys (after Bachelor's), (1 facility & 20 units)

- **Date completed initial requirements** mm/dd/yyyy

- **New Modality Training** [8 hours] (if applicable)

- **Continuing Experience adequate**? (2 facilities & 6 units/24 months)

- **Continuing Education**
  - CME/CEU Credits/year adequate? (15/36 months)
  - *If "n", then:*
  - *Number of CME/CEU's in 36 months*

You are reminded that <u>all</u> of the survey requirements in both MQSA and the regulations are applicable to each annual survey and the responsible physicist at the mammography facility. The preceding questions represent only what the inspectors will be evaluating **<u>on a routine basis</u>**. If the inspectors believe that it would be beneficial to their understanding of the performance of the facility or of the physicist, they may look for information not listed above.

Attachment A

Requirement for the Medical Physicist's Survey and Equipment Evaluations

21 CFR 900.12(d)(1)(iii)
Medical physicist. Each facility shall have the services of a medical physicist available to survey mammography equipment and oversee the equipment-related quality assurance practices of the facility. At a minimum, the medical physicist(s) shall be responsible for performing the surveys and mammography equipment evaluations and providing the facility with the reports described in paragraphs (e)(9) and (e)(10) of this section.

21 CFR 900.12(e)(9)
Surveys.

(i) *At least once a year, each facility shall undergo a survey by a medical physicist or by an individual under the direct supervision of a medical physicist. At a minimum, this survey shall include the performance of tests to ensure that the facility meets the quality assurance requirements of the annual tests described in paragraphs (e)(5) and (e)(6) of this section and the weekly phantom image quality test described in paragraph (e)(2) of this section.*

(ii) *The results of all tests conducted by the facility in accordance with paragraphs (e)(1) through (e)(7) of this section, as well as written documentation of any corrective actions taken and their results, shall be evaluated for adequacy by the medical physicist performing the survey.*

(iii) *The medical physicist shall prepare a survey report that includes a summary of this review and recommendations for necessary improvements.*

(iv) *The survey report shall be sent to the facility within 30 days of the date of the survey.*

(v) *The survey report shall be dated and signed by the medical physicist performing or supervising the survey. If the survey was performed entirely or in part by another individual under the direct supervision of the medical physicist, that individual and the part of the survey that individual performed shall also be identified in the survey report.*

21 CFR 900.12(e)(10)
Mammography equipment evaluations. Additional evaluations of mammography units or image processors shall be conducted whenever a new unit or processor is installed, a unit or processor is dissembled and reassembled at the same or a new location, or major components of a mammography unit or processor equipment are changed or repaired. These evaluations shall be used to determine whether the new or changed equipment meets the requirements of applicable standards in paragraphs (b) and (e) of this section. All problems shall be corrected before the new or changed equipment is put into service for examinations or film processing. The mammography equipment evaluation shall be performed by a medical physicist or by an individual under the direct supervision of a medical physicist.

Attachment B

QC Tests - Annual

21 CFR 900.12(e)(5)

Annual quality control tests. Facilities with screen-film systems shall perform the following quality control tests at least annually:

(i) *Automatic exposure control performance.*

(A) *The AEC shall be capable of maintaining film optical density within <plus-minus> 0.30 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility. If this requirement cannot be met, a technique chart shall be developed showing appropriate techniques (kVp and density control settings) for different breast thicknesses and compositions that must be used so that optical densities within <plus-minus> 0.30 of the average under phototimed conditions can be produced.*

(B) *After October 28, 2002, the AEC shall be capable of maintaining film optical density (OD) within <plus-minus> 0.15 of the mean optical density when thickness of a homogeneous material is varied over a range of 2 to 6 cm and the kVp is varied appropriately for such thicknesses over the kVp range used clinically in the facility.*

(C) *The optical density of the film in the center of the phantom image shall not be less than 1.20.*

(ii) *Kilovoltage peak (kVp) accuracy and reproducibility.*

(A) *The kVp shall be accurate within <plus-minus> 5 percent of the indicated or selected kVp at:*

(1) *The lowest clinical kVp that can be measured by a kVp test device;*

(2) *The most commonly used clinical kVp;*

(3) *The highest available clinical kVp, and*

(B) *At the most commonly used clinical settings of kVp, the coefficient of variation of reproducibility of the kVp shall be equal to or less than 0.02.*

(iii) *Focal spot condition. Until October 28, 2002, focal spot condition shall be evaluated either by determining system resolution or by measuring focal spot dimensions. After October 28, 2002, facilities shall evaluate focal spot condition only by determining the system resolution.*

(A) *System Resolution.*

(1) *Each X-ray system used for mammography, in combination with the mammography screen-film combination used in the facility, shall provide a minimum resolution of 11 Cycles/millimeters (mm) (line-pairs/mm) when a high contrast resolution bar test pattern is oriented with the bars perpendicular to the anode-cathode axis, and a minimum resolution of 13 line-pairs/mm when the bars are parallel to that axis.*

(2) *The bar pattern shall be placed 4.5 cm above the breast support surface, centered with respect to the chest wall edge of the image receptor, and with the edge of the pattern within 1 cm of the chest wall edge of the image receptor.*

(3) *When more than one target material is provided, the measurement in paragraph (e)(5)(iii)(A) of this section shall be made using the appropriate focal spot for each target material.*

(4) *When more than one SID is provided, the test shall be performed at SID most commonly used clinically.*

(5) *Test kVp shall be set at the value used clinically by the facility for a standard breast and shall be performed in the AEC mode, if available. If necessary, a suitable absorber may be placed in the beam to increase exposure times. The screen-film cassette combination used by the facility shall be used to test for this requirement and shall be placed in the normal location used for clinical procedures.*

(B) *Focal spot dimensions. Measured values of the focal spot length (dimension parallel to the anode cathode axis) and width (dimension perpendicular to the anode cathode axis) shall be within the tolerance limits specified in Table 1 in the Federal Register [Vol. 62, N0. 208, page 55990].*

(iv) *Beam quality and half-value layer (HVL). The HVL shall meet the specifications of Sec. 1020.30(m)(1) of this chapter for the minimum HVL. These values, extrapolated to the mammographic range, are shown in Table 2 in the Federal Register [Vol. 62, N0. 208, page 55990]. Values not shown in Table 2 may be determined by linear interpolation or extrapolation.*

(v) *Breast entrance air kerma and AEC reproducibility. The coefficient of variation for both air kerma and mA's shall not exceed 0.05.*

(vi) *Dosimetry. The average glandular dose delivered during a single cranio-caudal view of an FDA-accepted phantom simulating a standard breast shall not exceed 3.0 milligray (mGy) (0.3 rad) per exposure. The dose shall be determined with technique factors and conditions used clinically for a standard breast.*

(vii) *X-ray field/light field/image receptor/compression paddle alignment.*

(A) *All systems shall have beam-limiting devices that allow the entire chest wall edge of the x-ray field to extend to the chest wall edge of the image receptor and provide means to assure that the x-ray field does not extend beyond any edge of the image receptor by more than 2 percent of the SID.*

(B) *If a light field that passes through the X-ray beam limitation device is provided, it shall be aligned with the X-ray field so that the total of any misalignment of the edges of the light field and the X-ray field along either the length or the width of the visually defined field at the plane of the breast support surface shall not exceed 2 percent of the SID.*

(C) *The chest wall edge of the compression paddle shall not extend beyond the chest wall edge of the image receptor by more than one percent of the SID when tested with the compression paddle placed above the breast support surface at a distance equivalent to standard breast thickness. The shadow of the vertical edge of the compression paddle shall not be visible on the image.*

(viii) *Uniformity of screen speed. Uniformity of screen speed of all the cassettes in the facility shall be tested and the difference between the maximum and minimum optical densities shall not exceed 0.30. Screen artifacts shall also be evaluated during this test.*

(ix) *System artifacts. System artifacts shall be evaluated with a high-grade, defect-free sheet of homogeneous material large enough to cover the mammography cassette and shall be performed for all cassette sizes used in the facility using a grid appropriate for the cassette size being tested. System artifacts shall also be evaluated for all available focal spot sizes and target filter combinations used clinically.*

(x) *Radiation output.*

(A) *The system shall be capable of producing a minimum output of 4.5 mGy air kerma per second (513 milli Roentgen (mR) per second) when operating at 28 kVp in the standard mammography (moly/moly) mode at any SID where the system is designed to operate and when measured by a detector with its center located 4.5 cm above the breast support surface with the compression paddle in place between the source and the detector. After October 28, 2002, the system, under the same measuring conditions shall be capable of producing a minimum output of 7.0 mGy air kerma per second (800 mR per second) when operating at 28 kVp in the standard (moly/moly) mammography mode at any SID where the system is designed to operate.*

(B) *The system shall be capable of maintaining the required minimum radiation output averaged over a 3.0 second period.*

(xi) *Decompression. If the system is equipped with a provision for automatic decompression after completion of an exposure or interruption of power to the system, the system shall be tested to confirm that it provides:*

(A) *An override capability to allow maintenance of compression;*

(B) *A continuous display of the override status; and*

(C) *A manual emergency compression release that can be activated in the event of power or automatic release failure.*

21 CFR 900.12(e)(6)

Quality control tests--other modalities. For systems with image receptor modalities other than screen-film, the quality assurance program shall be substantially the same as the quality assurance program recommended by the image receptor manufacturer, except that the maximum allowable dose shall not exceed the maximum allowable dose for screen-film systems in paragraph (e)(5)(vi) of this section.

21 CFR 900.12(e)(7)

Mobile Units. The facility shall verify that mammography units used to produce mammograms at more than one location meet the requirements in paragraphs (e)(1) through (e)(6) of this section. In addition, at each examination location, before any examinations are conducted, the facility shall verify satisfactory performance of such units using a test method that establishes the adequacy of the image quality produced by the unit.

21 CFR 900.12(e)(8)

Use of test results.

(i) *After completion of the tests specified in paragraphs (e)(1) through (e)(7) of this section, the facility shall compare the test results to the corresponding specified action limits; or, for nonscreen-film modalities, to the manufacturer's recommended action limits; or, for post-move, preexamination testing of mobile units, to the limits established in the test method used by the facility.*

(ii) *If the test results fall outside of the action limits, the source of the problem shall be identified and corrective actions shall be taken:*

(A) *Before any further examinations are performed or any films are processed using the component of the mammography system that failed the test, if the failed test was that described in paragraphs (e)(1), (e)(2), (e)(4)(i), (e)(4)(ii), (e)(4)(iii), (e)(5)(vi), (e)(6), or (e)(7) of this section;*

(B) *Within 30 days of the test date for all other tests described in paragraph (e) of this section.*

Attachment C

THE MQSA QUALIFIACTIONS FOR MEDICAL PHYSICISTS

21 CFR 900.12(a)(3)
All medical physicists conducting surveys of mammography facilities and providing oversight of the facility quality assurance program under paragraph (e) of this section shall meet the following:

21 CFR 900.12(a)(3)(i)
Initial Qualifications

(A) *Be State licensed or approved or have certification in an appropriate specialty area by one of the bodies determined by FDA to have procedures and requirements to ensure that medical physicists certified by the body are competent to perform physics survey; and*

(B) ***(1)*** *Have a masters degree or higher in a physical science from an accredited institution, with no less than 20 semester hours or equivalent (e.g., 30 quarter hours) of college undergraduate or graduate level physics.*

(2) *Have 20 contact hours of documented specialized training in conducting surveys of mammography facilities.*

(3) *Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 10 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. After April 28, 1999, experience conducting surveys must be acquired under the direct supervision of a medical physicist who meets all the requirements of paragraphs (a)(3)(i) and (a)(3)(iii) of this section*; or

21 CFR 900.12(a)(3)(ii) Alternative Initial Qualifications

(A) *Have qualified as a medical physicist under paragraph (a)(3) of this section of FDA's interim regulations and retained that qualification by maintenance of the active status of any licensure, approval, or certification required under the interim regulations; and*

(B) *Prior to the April 28, 1999, have:*

(1) *A bachelor's degree or higher in a physical science from an accredited institution with no less than 10 semester hours or equivalent of college undergraduate or graduate level physics,*

(2) *Forty contact hours of documented specialized training in conducting surveys of mammography facilities, and*

(3) *Have the experience of conducting surveys of at least 1 mammography facility and a total of at least 20 mammography units. No more than one survey of a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement. The training and experience requirements must be met after fulfilling the degree requirement.*

21 CFR 900.12(a)(3)(iii)

(A) *Continuing education. Following the third anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed, the medical physicist shall have taught or completed at least 15 continuing education units in mammography during the 36 months immediately preceding the date of the facility's annual inspection or the last day of the calendar quarter preceding the inspection or any date in between the two. The facility shall choose one of these dates to determine the 36-month period. This continuing education shall include hours of training appropriate to each mammographic modality evaluated by the medical physicist during his or her surveys or oversight of quality assurance programs. Units earned through teaching a specific course can be counted only once towards the required 15 units in a 36-month period, even if the course is taught multiple times during the 36 months.*

21 CFR 900.12(a)(3)(iii)

(B) *Continuing experience. Following the second anniversary date of the end of the calendar quarter in which the requirements of paragraph (a)(3)(i) or (a)(3)(ii) of this section were completed or of April 28, 1999, whichever is later, the medical physicist shall have surveyed at least two mammography facilities and a total of at least six mammography units during the 24 months immediately preceding the date of the facility's annual MQSA*

inspection or the last day of the calendar quarter or any date in-between the two. The facility shall choose one of these dates to determine the 24-month period. No more than one survey of a specific facility within a 10-month period or a specific unit within a period of 60 days can be counted towards the total mammography unit survey requirement.

Attachment D

ATTESTATION FORM

Regarding Requirements of The Mammography Quality Standards Act

Attestation must include as much of the following information as possible:

Name of the institution/facility where the applicable training or mammography reading/interpreting, or other activity, took place; name of the course(s) or training (where applicable); the attendance, reading/interpreting, or other activity dates; and the supervising/responsible person (where applicable) for the institution/facility.
Please provide these details in the space below. Attach additional sheets if necessary.

I, _____, attest that, to the best of my knowledge and my belief, the following information provided in this declaration is true and correct. I understand that FDA may request additional information to substantiate the statements made in this declaration:

_____
_____
_____
_____
_____
_____
_____
_____

I understand that knowingly providing false information in a matter within the jurisdiction of an agency of the United States could result in criminal liability, punishable by up to $10,000 fine and imprisonment of up to five years, or civil liability under the MQSA, or both.

_____
Attestor's Signature and Title

_____
Date signed

Facility Name and Address (if applicable) including zip code:

_____
_____
_____
Facility ID Number (if applicable) from the Facility's MQSA certificate